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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,348	07/14/2006	Thomas Ivo Franciscus Herbert Cremers	484-US-PCT	5528

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EXAMINER	
RAO, SAVITHA M	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
09/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,348	CREMERS ET AL.	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-42 are currently pending in the instant application and are subject to a lack of unity requirement.

Election Restrictions

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1)A product and a process specially adapted for the manufacture of said product; or

(2)A product and process of use of said product; or

(3)A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4)A process and an apparatus or means specifically designed for carrying out the said process; or

(5)A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I: Claims 1 and 12-17 are drawn to a pharmaceutical composition comprising a compound which is a serotonin reuptake inhibitor, and another compound, which is a H_3 receptor antagonist, inverse agonist or partial agonist. **Please note additional Election of Species Requirement 1 and 2 outlined below.**

II. Group II: Claims 2 and 31-32 are drawn to a pharmaceutical composition comprising a compound which is a both H_3 receptor ligand (antagonist, inverse agonist

or partial agonist) and a serotonin reuptake inhibitor. **Please note additional Election of Species Requirement 1 and 2 outlined below.**

III. Group III: Claim 3 is drawn to a method of augmenting and/or providing faster onset of the therapeutic effect of a serotonin reuptake inhibitor, comprising administering to a patient in need thereof a therapeutically effective amount of H_3 receptor antagonist, inverse agonist or partial agonist. **Please note additional Election of Species Requirement 1 and 2 outlined below.**

IV. Group IV: Claims 4, 5-11, 18-21 are drawn to the method of treating depression or an affective disorder, comprising administering a therapeutically effective amount of a pharmaceutical composition described in Group **I** above. **Please note additional Election of Species Requirement 1, 2 and 3 outlined below..**

V. Group V: Claims 26-30, 33-36 and 39-40 are drawn to the method of treating depression or an affective disorder, comprising administering to a patient a therapeutically effective amount of a pharmaceutical composition described in **Group II** above. **Please note additional Election of Species Requirement 1, 2 and 3 outlined below.**

VI. Group VI: Claims 22 -24, 37-38 are drawn to a method of identifying compounds useful for the treatment of depression or an affective disorder.

VII. Group VII: Claim 25 and 41-42 are drawn to a compound that inhibits serotonin reuptake and has and IC50 value below 50 nM; and has an affinity to the H3 receptor.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups I to V lack unity of invention under 37 CFR 1.475 since the groups (I-V) are not unified by the same or corresponding special feature as detailed below.

The special technical feature in **Group I** is the pharmaceutical compositions which comprises of a compound which is a serotonin reuptake inhibitor and another compound which is a H_3 receptor antagonist, inverse agonist or partial agonist. This composition has two different compounds in the formulation.

The special technical feature in **Group II** is the pharmaceutical compositions which comprises of a compound which both a H_3 receptor antagonist, inverse agonist or partial agonist and a serotonin reuptake inhibitor, this composition has only one compound in the formulation.

The special technical feature in **Group III** is the method of augmenting and/or providing faster onset of the therapeutic effect of a serotonin reuptake inhibitor, comprising administering to a patient in need thereof a therapeutically effective amount of H_3 receptor antagonist, inverse agonist or partial agonist. This includes identifying those H_3 receptor antagonist, inverse agonist or partial agonist which work to increase the therapeutic effect of a serotonin reuptake inhibitor, identifying the mode of administration if the two has to be administered concomitantly or sequentially, development of an assay system to evaluate the augmentation effect and monitoring the patient for other untoward effects due to the combination treatment.

The special technical feature in **Group IV** is the method of treating depression or an affective disorder, comprising administering a therapeutically effective amount of a pharmaceutical composition described in Group I which involves diagnosis of the disease state, determining routes of administration and dosage requirements, administration to the patient, and monitoring of the prognosis of the disease with the final outcome of relieving or curing the patient.

The special technical feature in **Group V** is the method of treating depression or an affective disorder, comprising administering a therapeutically effective amount of a pharmaceutical composition described in Group II which involves diagnosis of the disease state, determining routes of administration and dosage requirements, administration to the patient, and monitoring of the prognosis of the disease with the final outcome of relieving or curing the patient.

The special technical feature in **Group VI** is the method of a method of identifying compounds useful for the treatment of depression or an affective disorder, which involves development of a screening procedure, screening combinatorial libraries, evaluating the data, determining IC50's and characterization of the compounds.

The special technical feature in **Group VII** is compound that inhibits serotonin reuptake and has and IC50 value below 50 nM; and has an affinity to the H3 receptor..

Accordingly there is no same or corresponding special technical features unifying Groups I-VII and thereby they lack unity.

Therefore, since in the instant application the claims are drawn to patentably distinct inventions, based on, different products, method of use and method of making

shown above, and according to 37 CFR 1.475(e): the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claims.

The claims, therefore, lack unity of invention.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. Specie election 1: This specie election applies to any of the **Groups I-V** detailed in the restriction requirement above**.** Applicant is required to elect single disclosed specie of serotonin reuptake inhibitor from those recited in instant claims 10 or 16, for e.g. Citalopram.

2. Specie election 2: This specie election applies to any of the **Groups I-V** detailed in the restriction requirement above**.** Applicant is required to elect single disclosed specie of H3 ligand from those recited in instant claims 11 and 17, for e.g. Proxifan

3. Specie election 3: This specie election applies only if electing either **Group IV or V** detailed in the restriction requirement above**.** Applicant is required to elect single disclosed specie of the affective disorder from those recited in instant claims 33 or 35 or 37 or 39, for e.g. anxiety disorders.

The species are structurally divergent, differ in their physical, chemical and biological properties and activities and thereby require searching in different class/subclasses and use of different search queries. Additionally, the different properties of the claimed species would also result in different efficacies and bioavailability profiles. In the instant case, the reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: 1-13 and 15-16 are generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii)identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-

5315. The examiner can normally be reached on Mon-Fri 8 am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
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